

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
David HUNG, <i>et al.</i>)	Examiner: Jennifer Kim
)	Group Art Unit: 1617
Serial No. 10/775,366)	
)	
Filed: February 10, 2004)	Attorney Docket No.: 12.016011 CON
)	
For: PREPARATION FOR BREAST DUCT)	
FLUID COLLECTION)	

RESPONSE TO OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

April 15, 2008

Sir:

The Office Action of January 25, 2008 has been received and considered. The Applicant respectfully requests reexamination and reconsideration of the above-identified application in view of the following remarks.

Remarks/Arguments

Claims 1-6 were originally pending. Claims 1 and 6 have been canceled. Claims 2-5 are currently pending. Claims 2-5 have been rejected.

Rejection of Claims 3 and 4 Under 35 U.S.C. 103(a)

Claims 3 and 4 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Tabar *et al.* (Radiology 149: 31-38, October 1983). Specifically, the Examiner states that Tabar teaches “...an intraductal injection comprising a standard needle (ductal access tool) comprising methylene blue dye and contrast material. Tabar teach that the most difficult step in galactography is gently inserting the blunt needle or cannula onto the secreting duct. And the procedure is painful. Tabar *et al.* does not expressly teach coating tip of a ductal access tool with anesthetic agent.” (page 3).

The Examiner then explains that it would have been obvious to one of ordinary skill in the art to modify the teaching of Tabar *et al.* and coat the tip of a ductal access tool with an anesthetic agent because the most difficult step in accessing breast duct in galactography is inserting the blunt needle or cannula into the secreting duct and the procedure is very painful. The Applicant respectfully disagrees with the Examiner’s interpretation of Tabar *et al.*

The Applicant respectfully traverses the foregoing rejection on the grounds that the Examiner has failed to establish a *prima facie* case of obviousness, since Tabar *et al.* fails to teach or suggest the claimed invention and further fail to provide the necessary motivation or expectation of success for the ordinarily skilled artisan to arrive at the claimed invention.

A new combination of elements can be patented “whether it be composed of elements all new, partly new or all old.” *Rosmount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546, 221 USPQ 1, 7 (CAFC 1984). The Court of Appeals for the Federal Circuit has forcefully stated that a claim rejection must provide a specific motivation in the art for combining elements from cited art in order to establish obviousness of a new combination.

“{C}ase law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art

references. ... Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. ... [Evidence of a suggestion, teaching, or motivation to combine] must be clear and particular. ... Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.' ... [A] reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the [cited] references teach or suggest their combination ... to yield the claimed invention," and a conclusion of obviousness based on such an analysis "as a matter of law, cannot stand." *In re Dembiczak*, 175 F.3d 994, 999, 1000, 50 USPQ2d 1614, 1617, 1618 (Fed. Cir. 1999), emphasis added.

Dembiczak involved patent claims to "a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern." *Dembiczak*, 996, 1616. The prior art cited by the Board included: a book describing how to teach children to make a "Crepe Paper Jack-O-Lantern;" a book describing a method of making a "paper bag pumpkin" by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint; a U.S. Patent describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material; design patents issued to Dembiczak; and prior art "conventional" plastic lawn or trash bags. The Federal Circuit held that the claimed pumpkin-style trash bag was not obvious because there was no clear, particular motivation to combine the cited references.

This holding of *Dembiczak* that evidence of motivation to combine must be clear and particular to establish obviousness has been emphasized over and over again by the Federal Circuit since *Dembiczak* was decided. It was strongly reemphasized in *Ruijs v. A.B. Chance Co.*, 57 USPQ2d 1161 (Fed. Cir. 2000):

In order to prevent a hindsight-based obviousness analysis, we have clearly established that the relevant inquiry for determining the scope and content of the prior art is whether there is a reason, suggestion, or motivation in the prior art or elsewhere that would have led one of ordinary skill in the art to combine the references. See, e.g., *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("[I]f the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been

motivated to select the references and to combine them to render the claimed invention obvious."); *In re Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617 ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."). "Determining whether there is a suggestion or motivation to modify a prior art reference is one aspect of determining the scope and content of the prior art, a fact question subsidiary to the ultimate conclusion of obviousness." *Sibia Neurosciences, Inc. v. Cadus Pharma, Corp.*, 225 F.3d 1349, 1356, 55 USPQ2d 1927, 1931 (Fed. Cir. 2000); *Tec Air, Inc. v. Denso Mfg., Inc.*, 192 F.3d 1553, 1359, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) (stating that the factual underpinnings of obviousness include whether a reference provides a motivation to combine its teachings with those of another reference).

... there is "a general rule that combination claims can consist of combinations of old elements as well as new elements," *Clearstream Wastewater Sys. v. Hydro-Action, Inc.*, 206 F.3d 1440, 1446, 54 USPQ2d 1185, 1189-90 (Fed. Cir. 2000), "[t]he notion . . . that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, § 103." *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1575, 1 USPQ2d 1593, 1603 (Fed. Cir. 1987); *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997) ("It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements."). *Ruiz* at 1167

The motivation cited in the present Office Action (page 3, last paragraph) for the proposed combination is as follows:

"One would have been motivated to make such a modification in order to achieve an expected benefit to numb the affected breast duct to be treated in order to ease the most difficult step in galactography."

This statement does not provide the clear, particular suggestion in the art for making the specific claimed combination as is required under *In re Dembiczak*. The claims here are no more obvious than those at issue in *Dembiczak*. No clear, particular suggestion or motivation in the prior art to make a "method of preparing a breast ductal for access and fluid collection comprising contacting a ductal orifice of a human breast with a tip of a ductal access tool coated with an anesthetic wherein contacting said ductal orifice with said anesthetic facilitates ductal access or

ductal fluid collection or both” as recited in claim 3 or a “ method of preparing a breast ductal for access and fluid collection comprising contacting a ductal orifice of a human breast with a tip of a ductal access tool coated with an anesthetic infusing a solution comprising an anesthetic into the duct through a lumen of the ductal access tool, wherein contacting said breast duct with said anesthetic facilitates ductal access or ductal fluid collection or both” as recited in claim 4 has been provided.

There is no teaching or suggestion in Tabar *et al.* for collecting ductal fluid. Both claims 3 and 4 of the present invention recite a method of preparing a breast ductal for access and fluid collection. In particular, claims 3 and 4 recite the limitation that contacting the breast duct with an anesthetic facilitates ductal fluid collection. There is simply no teaching or suggestion in Tabar *et al.* of the use of an anesthetic and certainly no description of the use of an anesthetic for the facilitation of the collection of ductal fluid.

Prima facie obviousness has not been established under such conditions. The obviousness rejection is based on hindsight to provide random elements of the claims. There is no clear, particular motivation in the references to reach the claimed invention. Withdrawal of this rejection under 35 USC 103(a) is respectfully requested.

Rejection of Claims 2 and 5 Under 35 U.S.C. 103(a)

Claims 2 and 5 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Tabar *et al.* (Radiology 149: 31-38, October 1983) in view of Stamler *et al.* (USP 5,380,758). Specifically, the Examiner states that Tabar teaches “...an intraductal injection comprising a standard needle (ductal access tool) comprising methylene blue dye and contrast material. Tabar teach that the most difficult step in galactography is gently inserting the blunt needle or cannula onto the secreting duct.

And the procedure is painful. Tabar *et al.* does not expressly teach coating tip of a ductal access tool with anesthetic agent.” (page 3). The Examiner then goes to state that Stamler *et al.* teaches S-nitrosothiol which alleviates smooth muscle contraction and spasm and facilitates procedures involving diagnostic instrumentation such as endoscopes.

The Examiner then explains that it would have been obvious to one of ordinary skill in the art to modify the method of Tabar *et al.* and incorporate an anesthetic agent and a muscle relaxing agent to the intraductal injection of Tabar *et al.* because an anesthetic agent is needed in galactography. Moreover, the Examiner argues that a muscle relaxing agent is useful in a fluid aspiration procedure because it facilitates and alleviates any muscle contraction or spasm.

The Applicant respectfully traverses the foregoing rejection on the grounds that the Examiner has failed to establish a *prima facie* case of obviousness, since neither Tabar *et al.* or Stamler, either alone or in combination, fails to teach or suggest the claimed invention and further fail to provide the necessary motivation or expectation of success for the ordinarily skilled artisan to arrive at the claimed invention.

As mentioned previously, the holding in *Dembiczak* requires that evidence of motivation to combine must be clear and particular to establish obviousness.

The motivation cited in the present Office Action (page 5, first paragraph) for the proposed combination is as follows:

“One would have been motivated to combine an anesthetic and a muscle relaxing agent in an intraductal injection in order to numb the pain and facilitates the procedure involving fluid aspiration in galactography.”

This statement does not provide the clear, particular suggestion in the art for making the specific claimed combination as is required under *In re Dembiczak*. The claims here are no more

obvious than those at issue in *Dembiczak*. No clear, particular suggestion or motivation in the prior art to make a method of preparing a breast for ductal fluid collection comprising contacting the nipple surface of a human breast with a composition comprising an anesthetic and a muscle-relaxing agent wherein contacting said nipple surface with the anesthetic and muscle-relaxing agent facilitates ductal fluid collection, as recited in claim 2 or a method of preparing a breast ductal for access and fluid collection comprising infusing a duct of a human breast with a solution comprising an anesthetic and a muscle-relaxing agent wherein infusing said duct with said solution facilitates ductal access or ductal fluid collection or both as recited in claim 5.

As mentioned previously, there is no teaching or suggestion in Tabar *et al.* for collecting ductal fluid. This deficiency cannot be remedied by the teaching of Stamler *et al.* which does not teach or suggest the collection of fluid from a breast duct. The Examiner argues that galactography involves fluid aspiration in a breast duct; however, there is no teaching or suggestion in Tabar *et al.* that fluid is collected from the breast duct. Claims 2 and 5 recite the limitation that contacting the breast duct with an anesthetic facilitates ductal fluid collection. There is simply no teaching or suggestion in Tabar *et al.* or in Stamler *et al.* of the use of an anesthetic or a muscle relaxing agent for the facilitation of the collection of ductal fluid.

Prima facie obviousness has not been established under such conditions. The obviousness rejection is based on hindsight from these disparate references to provide random elements of the claims. There is no clear, particular motivation in the references to reach the claimed invention. Withdrawal of this rejection under 35 USC 103(a) is respectfully requested.

CONCLUSION

It is believed that no fee is required for this submission. If any fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 502855, accordingly. If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a conference with Applicant, the Examiner is invited to contact Applicant's attorney at the number noted below.

Respectfully submitted,

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